Proposed Decision Memo for Home Use of Oxygen (CAG-00296N)

Decision Summary

CMS is seeking public comment on our proposed determination that there is sufficient evidence to conclude that the home use of oxygen is reasonable and necessary for Medicare beneficiaries with arterial oxygen partial measurements from 56 to 65 mmHg or whose oxygen saturation is at or above 89% and who therefore do not meet the current requirements for the home use of oxygen as detailed in Section 240.2 of the CMS NCD Manual, only when they are enrolled in an approved clinical trial.

We propose to issue a National Coverage Determination to cover the home use of oxygen for those beneficiaries meeting the qualifications described above who are enrolled subjects in clinical trials identified by CMS and sponsored by the National Heart, Lung & Blood Institute (NHLBI). As a condition of coverage, investigators must adhere to the provisions of HIPAA, the Privacy Act, PRA, and 45 CFR Part 46, if applicable.

We are requesting public comments on this proposed determination pursuant to section 731 of the Medicare Modernization Act. After considering the public comments and any additional evidence we will make a final determination and issue a final decision memorandum.

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Proposed Decision Memo

TO: Administrative File: CAG #00296

Home Use of Oxygen

FROM:

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SUBJECT: Proposed Decision Memorandum for Home Use of Oxygen

DATE: December 20, 2005

I. Proposed Decision

CMS is seeking public comment on our proposed determination that there is sufficient evidence to conclude that the home use of oxygen is reasonable and necessary for Medicare beneficiaries with arterial oxygen partial measurements from 56 to 65 mmHg or whose oxygen saturation is at or above 89% and who therefore do not meet the current requirements for the home use of oxygen as detailed in Section 240.2 of the CMS NCD Manual, only when they are enrolled in an approved clinical trial.

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We are requesting public comments on this proposed determination pursuant to section 731 of the Medicare Modernization Act. After considering the public comments and any additional evidence we will make a final determination and issue a final decision memorandum.

II. Background
Epidemiology
Chronic obstructive pulmonary disease (COPD) is the most common chronic lung disease in the United States and the most common indication for the use of supplemental oxygen. It is a progressive disorder of the airways that is characterized by a gradual loss of lung function and airflow limitation that is not fully reversible. The symptoms of COPD can range from chronic cough and sputum production to severe shortness of breath. In the U.S., the most important risk factor for the development of COPD is cigarette smoking. COPD is the fourth ranking cause of death in the U.S. and approximately 100,000 people per year die because of the condition. Approximately 12 million adults are diagnosed with the disorder each year.
Persons with COPD also suffer considerable morbidity related to their disease process, including: frequent physician visits or hospitalizations for symptom management, and decline in quality of life secondary to significant difficulty breathing and loss of functional ability.
Disease Process
One of the hallmarks of COPD is the noted abnormalities in the exchange of oxygen and carbon dioxide in the lungs. As a result, patients with COPD suffer from hypoxemia, a condition in which there is inadequate supply of oxygen to blood and tissues. In advanced stages of COPD, hypoxemia worsens to the point where patients require the use of supplemental oxygen therapy to maintain survival.
Interaction of the Intervention with the Disease Process

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Criteria have been developed in an attempt to identify those COPD patients who are most likely to benefit from supplemental/long-term oxygen therapy by prolonging survival and preventing further disease related complications such as end organ damage and further reduction in quality of life. It is generally recognized by the medical community that COPD patients with an arterial oxygen partial pressure measurement (PaO_2) ≤ 55 mmHg or those with PaO_2 measurements between 56-59 mmHg with evidence of end organ disease (pulmonary hypertension, cor pulmonale, polycythemia, arrhythmias, congestive heart failure, or impaired mental status) benefit from the use of long term oxygen therapy (LTOT). $\frac{2}{3}$ These criteria are based largely on two randomized controlled trials performed in 1980 and 1981. However, there is less scientific evidence evaluating the net health outcomes for the subgroup of COPD patients with PaO_2 measurements between 56-65 mmHg receiving LTOT as a therapeutic modality.

III. History of Medicare Coverage

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. § 1812 (Scope of Part A); § 1832 (Scope of Part B) § 1861(s) (Definition of Medical and Other Health Services). Provided that all coverage requirements are met, Medicare covers home use of oxygen as a supply to durable medical equipment (DME), which is referenced in section 1861(s)(6) of the Social Security Act. Equipment associated with delivering oxygen such as oxygen concentrators, portable, and stationary oxygen systems qualify as DME, while the oxygen contents serve as the DME supply. Thus, the home use of oxygen falls within the DME benefit category.

Medicare has a National Coverage Determination on Home Use of Oxygen (Rev. 1, 10-03-03) at Section 240.2 of the National Coverage Determinations Manual.

IV. Timeline of Recent Activities

August 16, 2005

CMS opened an internally generated National Coverage Determination (NCD) reconsideration to determine if there is sufficient evidence to change the current policy for beneficiaries having arterial oxygen partial pressure measurements in the range 56-65 mmHg.

The initial 30-day public comment period began.

September 16, 2005

End of public comment period.

V. FDA Status Oxygen itself is a naturally occurring element, readily available commercially from a variety of industrial and other sources. While the FDA regulates the equipment and delivery systems required for providing oxygen therapy, it does not regulate the use of oxygen. VI. General Methodological Principles When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve net health outcomes for patients. Improved net health outcomes is one of several considerations in determining whether an item or service is reasonable and necessary. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results. A detailed account of the methodological principles of study design that agency staff utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B. VII. Evidence A. Introduction We are providing a summary of the evidence we considered during our review. We will, of course, consider additional evidence submitted through the public comment period. The evidence reviewed to date in this proposed NCD includes the published medical literature on pertinent clinical trials of home oxygen.

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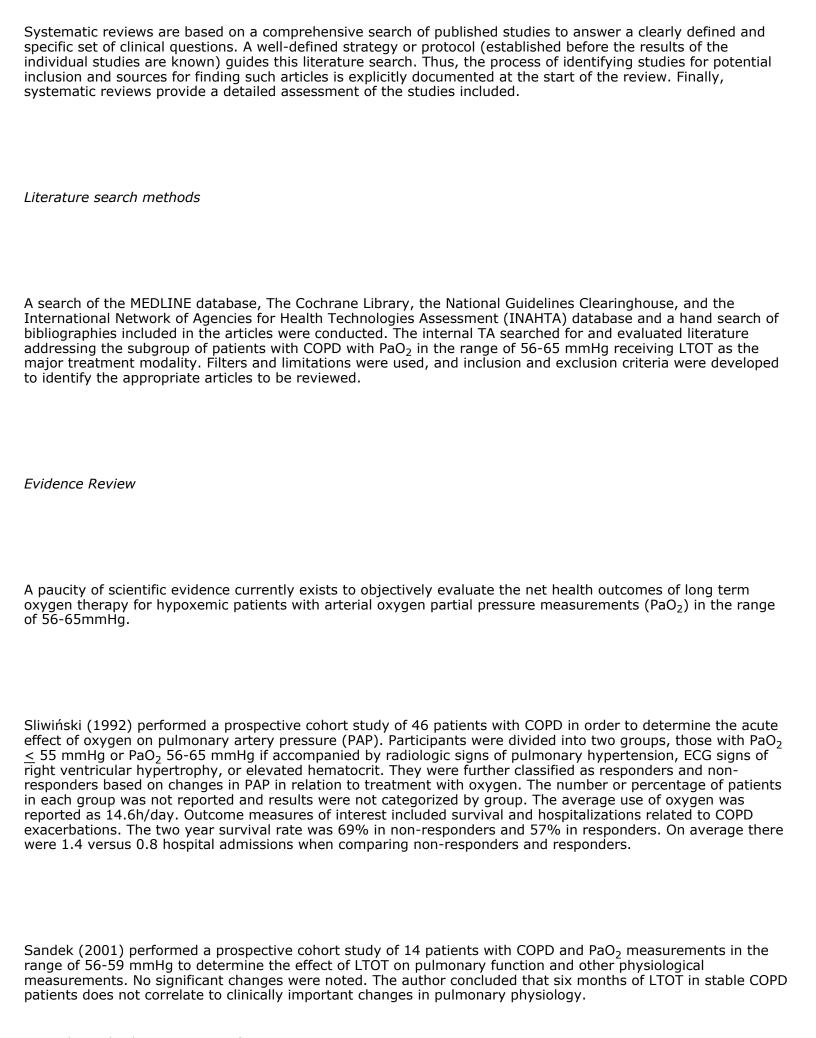
1. Question

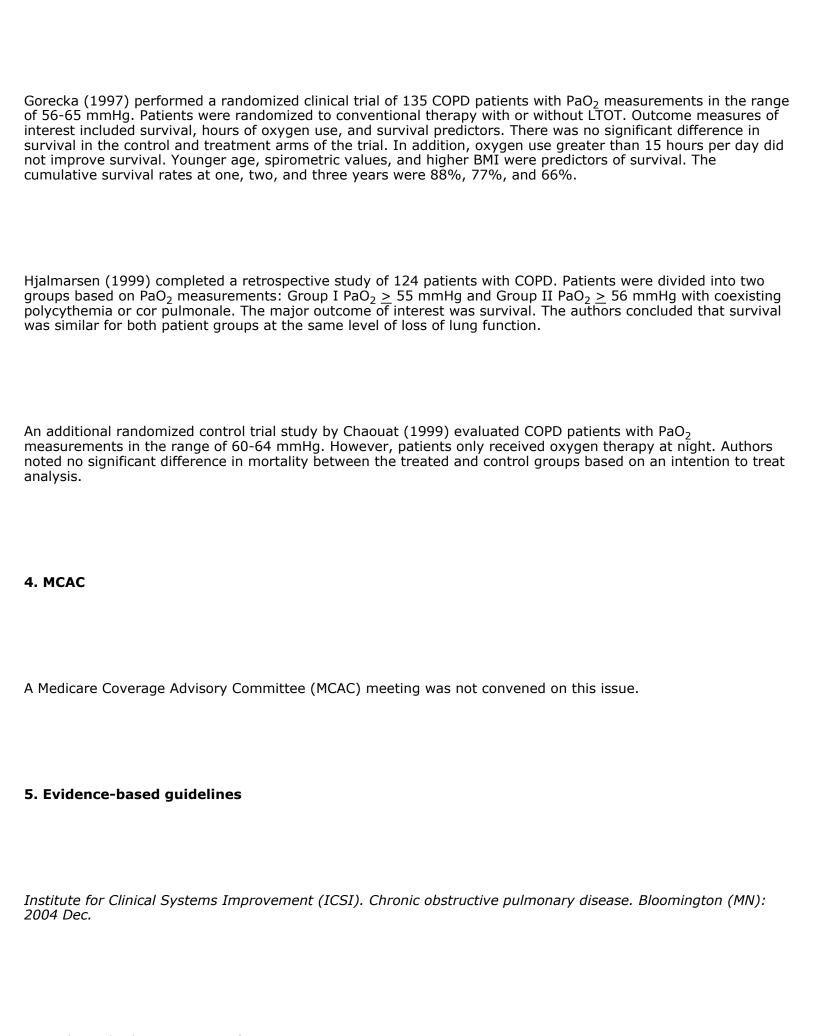
Is the quality of evidence adequate to conclude that the home use of oxygen can improve net health outcomes and is reasonable and necessary for Medicare beneficiaries who have arterial oxygen partial pressure measurements from 56 mmHg to 65 mmHg or whose oxygen saturation is at or above 89%?

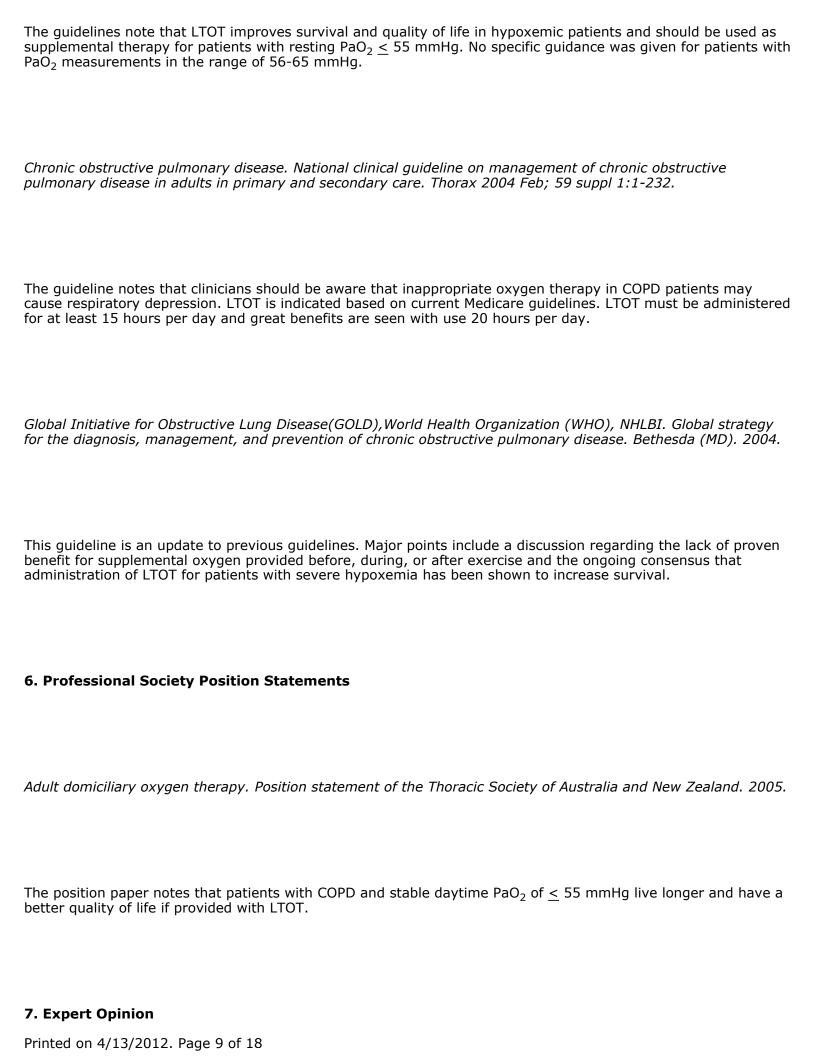
2. External technology assessments

In 2004, CMS requested an external technology assessment (TA) from the Agency for Healthcare Research and Quality (AHRQ) in order to summarize the available clinical and scientific evidence on the appropriateness and effective use of LTOT in patients with COPD. The TA authors concluded that there is insufficient scientific evidence to assess the survival benefit of patients with COPD and PaO₂ measurements in the range of 56-65 mmHg. This conclusion is based on the lack of scientifically rigorous evidence used to guide the use of LTOT in COPD patients. In addition, the majority of studies reviewed by the TA authors reported findings for the subgroup of patients with severe resting hypoxemia or moderate hypoxemia with certain advanced manifestation of disease such as concomitant cardiac impairment. Inconsistencies in identifying or reporting evidence regarding nonmortality outcomes such as rates of hospitalization, improvement in lung physiology, and quality of life measures were also noted by the TA authorities. This information was subsequently presented as part of an expert working group convened by NHLBI to discuss LTOT in May of 2004. The NHLBI report cited the efficacy of LTOT in patients with moderate resting hypoxemia as an important future research initiative. Hours of oxygen utilization, therapeutic benefits independent of survival, and the identification of specific population subgroups such as those with pulmonary hypertension or low BMI were identified as important to informing the current body of evidence regarding COPD patients and LTOT as a therapeutic modality.

3. Internal technology assessments

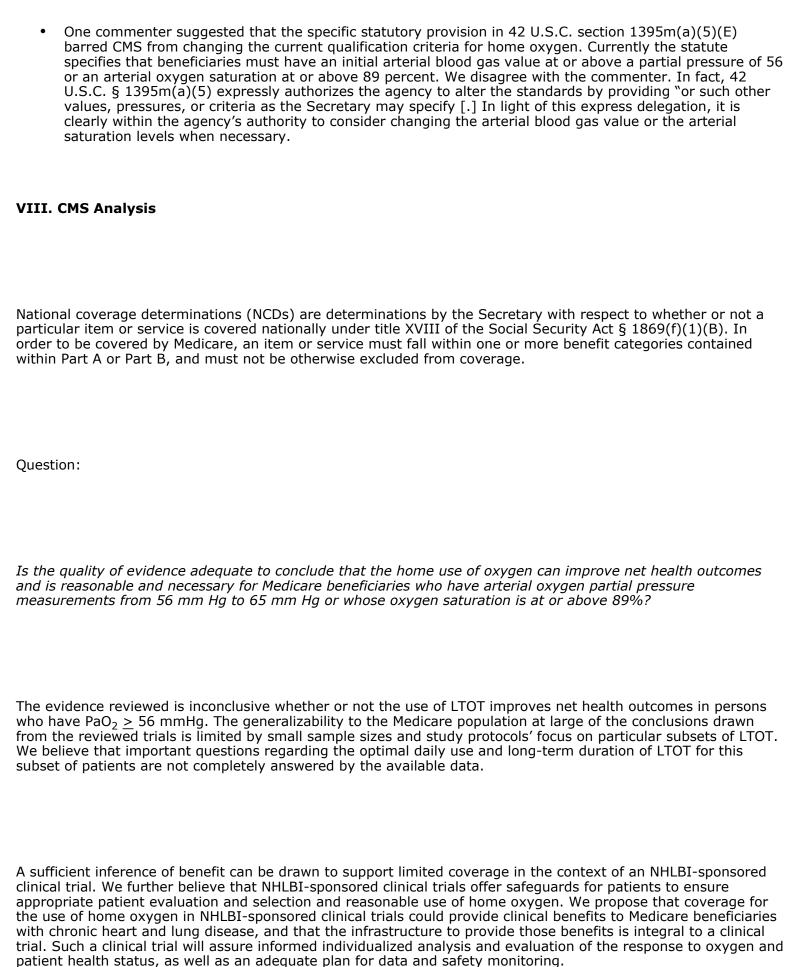






Apart from the public comments discussed below, we have not currently received any expert opinions on the home use of oxygen for beneficiaries who do not meet the requirements of Section 240.2 of the CMS NCD Manual.
8. Public Comments
Initial public comments
CMS utilizes the initial public comments to inform its proposed decision. We will respond in detail to the final public comments on this proposed decision.
During the initial public comment period, CMS received written statements from three respiratory therapists, five associations, two physicians and six individuals (many of whom work in the health care field). The comments are summarized below.

- CMS should increase coverage to include beneficiaries having oxygen partial pressure measurements in the range of 56-65 mmHg.
- Coverage of oxygen for beneficiaries having oxygen partial pressure measurements in the range of 56-65 mmHg could reduce costs in other expenditures, such as hospital and emergency room visits.
- CMS should consider covering oxygen for those patients in a nursing home.
- CMS should reconsider the criteria and reimbursement for Independent Testing Facilities.
- Medi-Cal and Medicaid usually apply the same policy as Medicare so this would help those patients as well.
- CMS should maintain the coverage for group II patients until randomized controlled studies are available to contradict from NOTT and BMRC.
- It may be beneficial to expand coverage to a subset of group II patients to include PaO2 levels up to 65 mmHg.
- The subset of patients in group II should be retested/recertified for continuing use of oxygen so long as the payment policy allows physicians to bill for such retesting.
- CMS should consider guidance by NIH and other research bodies in the May 10-11, 2004 LTOT in COPD working group executive summary.



IX. Proposed Conclusion

CMS is seeking public comment on our proposed determination that there is sufficient evidence to conclude that the home use of oxygen is reasonable and necessary for Medicare beneficiaries with arterial oxygen partial measurements from 56 to 65 mmHg or whose oxygen saturation is at or above 89% and who therefore do not meet the current requirements for the home use of oxygen as detailed in Section 240.2 of the CMS NCD Manual, only when they are enrolled in an approved clinical trial.

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APPENDIX A [PDF, 69KB]

APPENDIX B

General Methodological Principles of Study Design

(Section VI of the Decision Memorandum)

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve net health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were
 assigned (intervention or control). This is important especially in subjective outcomes, such as pain or
 quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by
 either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

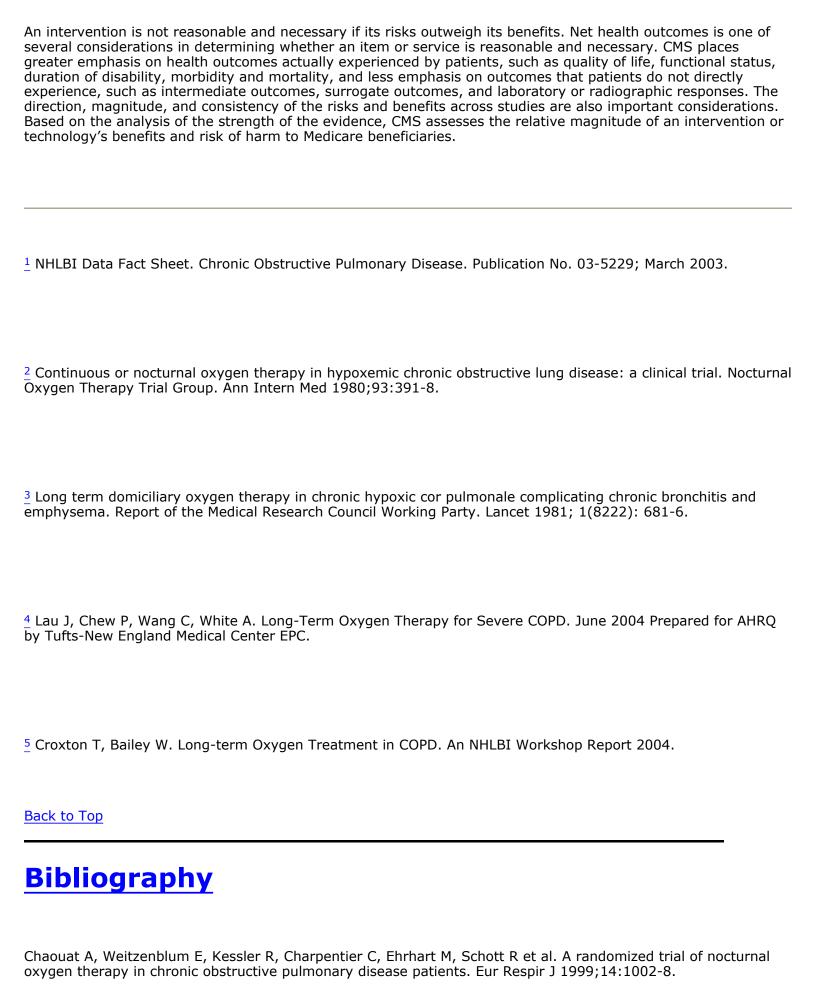
When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.





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